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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/404,520	09/23/99	CAO Y	04983.0207.U

EXAMINER	
SIRZELECKA, T	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/404,520	CAO ET AL.	
	Examin r	Art Unit	
	Teresa E Strzelecka	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented claims 19-26 in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct cells (bacterial, fungal, plant, mammalian, bird, fish) and organisms (plants, mammals, fish, birds) to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 10-17, 27, 28, 31-44 and claims 19-20, 22-24 and 26 (in part), drawn to substantially purified nucleic acid molecules from the *E. nidulans* genome, their complements and homologues, collections of such purified nucleic acid and primers for their amplification and cells transformed with the nucleic acid molecules. Classified in class 536, subclass 23.1.

If Group I is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the bacterial cells.

II. Claim 18, drawn to a substantially purified polypeptide encoded by a polynucleotide of claim 1, classified in class 530, subclass 300.

III. Claims 19-26 (in part), drawn to transformed fungal cells, classified in class 435, subclass 254.11.

If Group III is elected, claims 19-26 will be examined to the extent that they read on the fungal cells.

IV. Claims 19-20, 22-24 and 26 (in part), drawn to transformed plant cells, classified in class 435, subclass 419.

If Group IV is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the plant cells.

V. Claims 19-20, 22-24 and 26 (in part), drawn to transformed animal cells, classified in class 435, subclass 325.

If Group V is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the animal cells.

VI. Claims 19-20, 22-24 and 26 (in part), drawn to transgenic mammals, classified in class 800, subclass 14.

If Group VI is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the transgenic mammals.

VII. Claims 19-20, 22-24 and 26 (in part), drawn to transgenic birds, classified in class 800, subclass 19.

If Group VII is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the transgenic birds.

VIII. Claims 19-20, 22-24 and 26 (in part), drawn to transgenic fish, classified in class 800, subclass 20.

If Group VIII is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the transgenic fish.

IX. Claims 19-20, 22-24 and 26 (in part), drawn to transgenic plants, classified in class 800, subclass 295.

If Group IX is elected, claims 19-20, 22-24 and 26 will be examined to the extent that they read on the transgenic plants.

X. Claims 45 and 46, drawn to polynucleotide-based methods of screening, classified in class 435, subclass 6.

XI. Claims 29-30, drawn to a computer readable medium having recorded thereon nucleotide sequences, classified in class D14, subclass 474.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

4. Inventions I and III-V are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Groups III-V are drawn to transformed cells. These are differing biochemical entities having differing biochemical properties, structures and effects.

Inventions III-V would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

5. Inventions I and VI-IX are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Groups VI-IX are drawn to transgenic organisms. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI-IX would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

6. Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different manner, such as mutation detection, rather than in the method of Group X.

7. Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the computer readable medium of Group XI could be used in an entirely different manner, such as to store music files, rather than the nucleic acid sequences of Group I.

8. Inventions II and III-V are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the cells of Inventions III-V. While the polypeptides of Invention II may be present in cells of Inventions III-V, the biochemical activities of each

Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

9. Inventions II and VI-IX are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the transgenic organisms of Inventions VI-IX. While the polypeptides of Invention II may be present in the transgenic organisms of Inventions VI-IX, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

10. Inventions II and X-XI are separate and distinct, as the polypeptides of Invention II are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

11. Inventions III and IV-V are separate and distinct, as the claims of Invention III are drawn to transformed fungal cells, while the claims of Groups IV-V are drawn to transformed plant and animal cells, respectively. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions IV-V would require searching in areas unrelated to fungal cells, and as such, would require an undue burden on the examiner if not restricted.

12. Inventions III and VI-IX are separate and distinct, as the claims of Invention III are drawn to transformed fungal cells, while the claims of Groups VI-IX are drawn to transgenic organisms. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI-IX would require searching in areas unrelated to fungal cells, and as such, would require an undue burden on the examiner if not restricted.

13. Inventions III and X-XI are separate and distinct, as the fungal cells of Invention III are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require

search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

14. Inventions IV and V are separate and distinct, as the claims of Invention IV are drawn to transformed plant cells, while the claims of Group V are drawn to transformed animal cells. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention V would require searching in areas unrelated to plant cells, and as such, would require an undue burden on the examiner if not restricted.

15. Inventions IV and VI-IX are separate and distinct, as the claims of Invention IV are drawn to transformed plant cells, while the claims of Groups VI-IX are drawn to transgenic organisms. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI-IX would require searching in areas unrelated to plant cells, and as such, would require an undue burden on the examiner if not restricted.

16. Inventions IV and X-XI are separate and distinct, as the plant cells of Invention IV are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

17. Inventions V and VI-IX are separate and distinct, as the claims of Invention V are drawn to transformed animal cells, while the claims of Groups VI-IX are drawn to transgenic organisms. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VI-IX would require searching in areas unrelated to animal cells, and as such, would require an undue burden on the examiner if not restricted.

18. Inventions V and X-XI are separate and distinct, as the animal cells of Invention V are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require

search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

19. Inventions VI and VII-IX are separate and distinct, as the claims of Invention VI are drawn to transgenic mammals, while the claims of Groups VII-IX are drawn to transgenic birds, fish and plants, respectively. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VII-IX would require searching in areas unrelated to transgenic mammals, and as such, would require an undue burden on the examiner if not restricted.

20. Inventions VI and X-XI are separate and distinct, as the transgenic mammals of Invention VI are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

21. Inventions VII and VIII-IX are separate and distinct, as the claims of Invention VII are drawn to transgenic birds, while the claim of Groups VIII-IX are drawn to transgenic fish and plants, respectively. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions VIII-IX would require searching in areas unrelated to transgenic birds, and as such, would require an undue burden on the examiner if not restricted.

22. Inventions VII and X-XI are separate and distinct, as the transgenic birds of Invention VII are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

23. Inventions VIII and IX are separate and distinct, as the claims of Invention VIII are drawn to transgenic fish, while the claims of Group IX is drawn to transgenic plants. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention IX

would require searching in areas unrelated to transgenic fish, and as such, would require an undue burden on the examiner if not restricted.

24. Inventions VIII and X and XI are separate and distinct, as the transgenic fish of Invention VIII are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

25. Inventions IX and X-XI are separate and distinct, as the transgenic plants of Invention IX are not used in the methods of either Invention X or in Invention XI. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted

Sequence Election Requirement Applicable to All Groups

26. In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequence (See MPEP 803.04).

27. MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

28. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

29. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

30. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
February 2, 2001

KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

2/8/01

Kenneth R. Horlick, Ph.D.